



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/115,589	07/15/98	VAN EYK	J 12917

09/115,589 07/15/98 VAN EYK

EXAMINER	
ART UNIT: S	PAPER NUMBER

DATE MAILED: 10/4/00

02/10/00

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HM12/0210

AIR MAIL

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents and Trademarks

Responsive to Communication Filed \_\_\_\_\_.

The enclosed is a correct copy of a reference relating to the last Office action. The correction is indicated below.

THE PERIOD FOR RESPONSE OF \_\_\_\_\_ / MONTHS SET IN SAID OFFICE ACTION IS  
RESTARTED TO BEGIN WITH THE DATE OF THIS LETTER.

Part 1 - Correct Reference Citation

Bemailed Office action dated 10-5-98  
was mailed to wrong address

by \_\_\_\_\_

Examiner

DONNA CHAPMAN  
SUPERVISORY, LEGAL

INSTRUMENTS EXAMINER

GROUP 1600

703-308-3081

Part 2 - Correct Reference Furnished:

by \_\_\_\_\_

Reference Order Center

enc.

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-28, 31-32, and 35-36, drawn to a method and kit for assessing muscle damage, classified in class 435, subclass 7.1+, for example.

Group II. Claims 29-30 and 33-34, drawn to a compound (kit lacks patentable weight), classified in class 530, subclass 350+, for example.

Group III. Claims 37-40, drawn to a method of screening for an agent which modulates the level of a myofilament protein modification product, classified in class 435, subclass 7.1+, for example.

Group IV. Claims 41-52, drawn to a method of assessing muscle damage in a subject by specific binding assay, complex formation, and profile characterization, classified in class 436, subclass 503+, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Groups II and I, III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II can be used to assess muscle damage directly or be used as an agent which modulates muscle damage.

3. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to different methods; restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Groups I, III-IV are directed to methods that comprise distinct process steps and use distinct products that are different physically, structurally, and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other. In the instant case the different methods are distinct, each from the other, because they differ with respect to goals, (e.g. method of screening vs. diagnosis vs. profile characterization).

4. Claims 9 and 30 are generic to a plurality of disclosed patentably distinct species comprising: a) antibody or functional fragment; b) protein, protein fragment, or peptide; and c) peptidomimetic. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims 20, 21, 33, 34, 39, 40, 43, and 44 are generic to a plurality of disclosed patentably distinct species comprising: a) troponin I; b) troponin T; c) troponin C; d)  $\alpha$ -actinin; and e)

myosin light chain 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Claims 22-24 are generic to a plurality of disclosed patentably distinct species comprising: a) residues 194-210 of troponin I; and b) residues 1-193 of troponin I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claims 25-27 are generic to a plurality of disclosed patentably distinct species comprising: a) residues 20-199 of myosin light chain 1; and b) residues 1-19 of myosin light chain 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the literature searches required for the inventions are not co-extensive and therefore references that would anticipate one invention would not necessarily anticipate or even make obvious the other invention, a search burden exists, and restriction for examination purposes as indicated is proper. Furthermore, there are different issues for the search and examination of each, which would also be unduly burdensome. In addition, prior art searches require non-patent literature searches and the search for the invention of any group would not be expected to reveal all the relevant references for the inventions of the remaining groups.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1645

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*SG*

Stephen Gucker

October 1, 1999



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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